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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,340	08/27/2001	Gust H. Bardy	032580.0024.UTL	5225

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,340

Applicant(s)

BARDY ET AL. *JB*

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-279 is/are pending in the application.
- 4a) Of the above claim(s) 246-279 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 184-244 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims rejected are 1-9,11,12,14,15,17-42,45-47,51-57,60-70,72,73,75,76,78-108,112
118,121-131,133,134,136,137,139-164,167-169,173-179,182 and 183.

Continuation of Disposition of Claims: Claims objected to are 10,13,16,43,44,48-50,58,59,71,74,77,109-
111,132,135,138,165,166,170-172,180 and 181.

DETAILED ACTION

Election/Restrictions

1. Claims 246-279 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Specification

2. The disclosure is objected to because of numerous errors regarding the referencing of elements in the drawings. Furthermore, the status of the cross-referenced applications on page 1 of the specification must be updated. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 49, 110, 171 are objected to because of the following informalities: reference to the backing layer lacks antecedent basis. The examiner will assume dependency on claims 48, 109 and 170 respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 8, 9, 11, 12, 14, 21, 22, 40-42, 45-47, 56, 57, 62, 65, 66, 69, 70, 72, 73, 75, 82, 83, 95, 101-103, 106-108, 117, 118, 123, 126, 127, 130, 131, 133, 134, 136, 143, 144, 156-158, 162-164, 167-169, 178 and 179 are rejected under 35 U.S.C. 102(b) as being anticipated by Moe, Jr. (Pat. No. 3,566,860).

Regarding claim 1, Moe, Jr. shows an electrode 12 coupled to a riser 14 with a head 16 coupled to the riser. While the preamble was considered, the reference to subcutaneous implantation was considered to be merely a statement of intended use

absent any structure in the body of the claim that would limit the lead electrode to this locale.

Regarding claim 41 and claims with similar limitations, where one measures length by no means limits the apparatus in any way structurally.

Regarding claim 42 and claims with similar limitations, the examiner will consider in this instance the proximal end of the electrode to be the topside of the electrode 12, and the distal end to be the bottom-side of electrode 12.

Regarding claim 45 and claims with similar limitations, the examiner considers element 18 to comprise a foundation. One could also consider elements 26 and 28 to comprise a foundation.

Regarding claim 46 and claims with similar limitations, since one may arbitrarily define what is a top surface of the foundation and what is a bottom surface of the riser, the recited relationship can always be met.

Regarding claims 62 and 123, note the comments made in the rejection of claim 1 concerning preamble interpretation.

6. Claims 1-3, 6, 7, 11, 12, 14, 19-22, 40-42, 45, 46, 63, 64, 67, 68, 72, 73, 75, 80-83, 106, 123-125, 128 and 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Corasanti (Pat. No. 3,841,312).

The rejection of claims under Corasanti substantially parallel the rejection of claims under Moe, Jr. with the exception that the lead electrode assembly of Corasanti is made out of metal (particularly a nickel alloy).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15, 17, 18, 23-39, 51-55, 60, 61, 76, 78, 79, 84-94, 96-100, 104, 105, 112-116, 121, 122, 137, 139-142, 145-155, 159-161, 173-177, 182 and 183 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moe, Jr. (Pat. No. 3,566,860).

With reference to claim 15 and claims with similar limitations, although Moe, Jr. does not concern himself with the length of the riser, the examiner considers the riser of Moe, Jr. to necessarily fall within the recited range based on obvious design constraints. Clearly one would not manufacture a riser for use in the system of Moe, Jr. that is so long that it sacrifices the stability of the electrode on the body (i.e., acting like a cantilever beam with the force of the lead pulling the electrode off the body due to the higher torque associated with the increased length). Nor would one manufacture a riser that is so short as to make it difficult to attach a lead to the head.

Concerning claims 17 and 18 as well as claims with similar limitations, the examiner did not require restriction between embodiments wherein the electrode was a mesh or a flat sheet or a polymer or a metal because such variations were not considered to be patentably distinct. Since the examiner has found the embodiment comprising a flat sheet, the use of a metal mesh is also considered to be an obvious variant.

Concerning claim 23, although Moe, Jr. does not elaborate on the exact dimensioning of the electrode area, the examiner takes Official Notice that electrodes of the type disclosed by Moe, Jr. typically would have a surface area falling within the recited range.

Regarding claims 24-28 and claims with similar limitations, although Moe, Jr. does not show the use of a lead coupled to the electrode, the use of such a lead is an absolute necessity if the device is to function. The examiner takes Official Notice that leads of this nature comprise one or more electrical conductors surrounded by insulation.

Concerning claim 29, the examiner considers a typical lead for use in the Moe, Jr. system to fall in the range recited and takes Official Notice to this effect. Likewise concerning claims 30 and 31, no criticality has been recited by the applicant for the particular length of lead used. The examiner considers it a matter of obvious design as

to what the final lead length should be, dependent upon the situation at hand (e.g., an electrode vest with integrated leads would not require a lengthy cable to connect each electrode to the monitor).

Concerning claims 32 and 33, the applicant appears to be defining the invention in terms of non-elements of the invention. The applicant is not claiming a set of leads with a plurality of preset lengths varying by approximately 10 cm –simply that the lead used is one of a plurality of preset lengths. Whether a lead falls into this category is simply a matter of how many different leads a manufacturer may produce.

Regarding claims 34 and 35, the examiner considers it axiomatic that any lead used in the device of Moe, Jr. would have a proximal end and a distal end, with at least one end coupled to the electrode via a lead fastener.

Regarding claims 36-38, since one can arbitrarily define a line in any direction, there are an infinite number of lines along which the riser is connected to the electrode. One for example can define a line through the axis of the riser and consider such a line to encompass a point at which the riser is attached to the electrode and also intersects the lead fastener.

Regarding claim 39, considering the relatively large range recited and typical neck or riser lengths associated with electrodes of the type disclosed by Moe, Jr., those of ordinary skill in the art would have found it axiomatic that the riser of Moe, Jr. be within this recited range for practicality purposes.

Concerning claims 51 and 52, although Moe, Jr. shows a cover (element 18), it is not clear that it is molded. The examiner takes Official Notice that it is old and well-known in the prior art of record to produce an element such as shown by reference numeral 18 by molding processes. In this instance, the examiner considers elements 26 and 28 to represent a foundation.

Regarding claim 53, since one can arbitrarily define what is to be the top and the bottom of the electrode, the examiner considers the cover 18 to be a skirt that partially covers a bottom surface of the electrode (it should be noted that the skirt shown in Fig. 4 does not completely overlie the electrode about the riser/neck 14).

Allowable Subject Matter

9. Claims 184-244 are allowed.

There does not appear to be a teaching in the prior art of record for incorporating the recited electrode, riser and head with a housing for an implantable cardioverter-defibrillator.

10. Claims 10, 13, 16, 43, 44, 48-50 58, 59, 71, 74, 77, 109-111, 119, 120, 132, 135, 138, 165, 166, 170-172, 180 and 181 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


12. The lengthy IDS submitted on November 14, 2003 was not accompanied by any of the listed references and therefore does not meet the requirements of §1.98.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaezle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
January 11, 2004


KENNEDY SCHAEZLE
PRIMARY EXAMINER